UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

WILMARINE HILL, wife, and LARRY HILL, husband and their marital community, Plaintiffs, v. FRESENIUS USA, INC.; FRESENIUS USA MANUFACTURING, INC.; FRESENIUS USA MARKETING, INC.; FRESENIUS USA SALES, INC.; FRESENIUS MEDICAL CARE HOLDINGS, INC. d/b/a FRESENIUS MEDICAL CARE NORTH AMERICA; Defendants.	COMPLAINT and JURY TRIAL DEMAND

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Plaintiffs, Wilmarine Hill and Larry Hill and their marital community, by and through the undersigned counsel, bring this Complaint and allege against Defendants as follows:

I. INTRODUCTION

1. On March 29, 2012, the U.S. Food and Drug Administration (FDA) issued a Class 1 recall of GranuFlo and NaturaLyte, dialysis products manufactured by Fresenius Medical Care. The use of either product can result in high bicarbonate levels that can cause metabolic alkalosis – a significant risk associated with low blood pressure, hypokalemia, hypoxemia, hypercapnia, and cardiac arrhythmia, which may cause, among other things, heart attacks, strokes and even death.

2. Class 1 recalls are the most serious type of recall and involve situations in which there is a reasonable probability that use of these products will cause adverse health consequences – or death.

3. Medical research links GranuFlo and NaturaLyte to high bicarbonate levels that can cause a variety of health problems including:

- Cardiopulmonary arrest
- Heart problems
- Metabolic alkalosis
- Low blood pressure
- Sudden myocardial infarction or heart attack
- Stroke, and
- Death

4. The GranuFlo and NaturaLyte recall states that the company failed to disclose vital information to the FDA and health-care providers about the possible risk of high bicarbonate levels when administering these products.

5. In response to the high rate of cardiac arrests that occurred in Fresenius Medical Care ("FMC") clinics in 2010, the company submitted an internal memo to its own dialysis clinics on November 4, 2011.

6. After the FDA received an anonymous copy of the November 4th internal memo, company executives were forced to issue an urgent public product warning and recall to its customers that GranuFlo and NaturaLyte were associated with elevated bicarbonate levels and an increased risk for cardiopulmonary arrest and sudden cardiac death as well as stroke and other serious or even fatal complications.

7. Fresenius conducted a case-control study that evaluated risk factors in hemodialysis patients who suffered from cardiopulmonary arrest in FMC facilities compared to other dialysis patients within the same facilities between January 1 and December 31, 2010. This study identified 941 patients in 667 FMC facilities who had cardiopulmonary (CP) arrests within the facilities. Looking at the data for these 941 patients, the study found that the patients' risk of cardiopulmonary arrest was up to six times higher if they had an elevated pre-dialysis bicarbonate level.

8. Cardiac death is recognized as the number one cause of death for dialysis patients, accounting for 59% of those deaths. By 2010, the medical community had concluded that these cardiovascular-related deaths were not due primarily to atherosclerotic (plaques and arterial stiffening) disease, but rather uremic cardiomyopathy, characterized by left ventricular hypertrophy (LVH), LV dysfunction, and LV dilatation. This conclusion caused many in the

medical community, including FMC, to research the issue – too late to prevent GranuFlo and NaturaLyte related injuries.

9. This case arises out of injuries and medical complications caused by a heart attack following the use of GranuFlo. On or about September 23, 2008, Wilmarine Hill went in for her typical three hour dialysis treatment at Fresenius Medical Care Gallipolis, in Gallipolis, Ohio. On information and belief, Fresenius' products NaturaLyte and/or GranuFlo were administered to Ms. Hill as part of that treatment. At the end of her dialysis treatment, Ms. Hill began experiencing a number of debilitating and frightening symptoms associated with a heart attack. She suddenly became unresponsive and was in obvious distress, and clinic staff initiated advanced cardiac life support protocols. Ms. Hill was partially revived after many minutes passed, and she was then transported to Riverside Methodist Hospital in Columbus, Ohio. Upon arrival at the hospital, Ms. Hill was found to be in ventricular fibrillation and multiple defibrillator shocks were administered. She was then intubated and transferred to the ICU, and remained hospitalized for another eight days. The heart attack was so severe that Ms. Hill required a pacemaker placement and endured a long and involved course of treatment and rehabilitative care. Even with the benefit of that long course of treatment, Ms. Hill continues to suffer from the damage caused by her heart attack. She cannot walk very well, and must use a walker while ambulating at home and a wheel chair when she goes out. Her husband and family members must help with many of her personal needs as well as the cooking and cleaning. Her husband, Larry Hill, has been deprived of the personal benefits and satisfaction that he enjoyed as a result of his marital relationship with Ms. Hill and which he had enjoyed prior to her suffering the heart attack caused by Fresenius' defective products. Ms. Hill's heart attack was not

the result of the renal failure that required her to undergo dialysis, but rather was brought on by Fresenius' defective NaturaLyte and/or GranuFlo products, as described more fully below.

10. Ms. Hill was never warned of the significant and serious risks associated with the use of Fresenius' GranuFlo and NaturaLyte products. She was never told that the use of those products in connection with her necessary dialysis treatments could increase her risk of stroke, that it could increase her risk of heart attack by up to six-fold, or that the use of those products in connection with her dialysis treatments could subject her to other serious and even fatal risks.

11. Ms. Hill's heart attack and related injuries, as with the injuries and deaths suffered by thousands of similarly situated dialysis patients all over the United States, was preventable. These injuries and deaths occurred because the medical providers administering Defendants' defective products were unaware that these products caused elevated levels of bicarbonate resulting in an increased risk for cardiopulmonary arrest and sudden cardiac death as well as stroke and other serious or even fatal complications. Fresenius failed to adequately investigate or study its GranuFlo product prior marketing it for use in dialysis beginning in 2003. Despite its initial failure to study GranuFlo, Fresenius knew or should have known of its dangerous propensities as early as 2005, long before its 2011 internal memorandum or the 2012 FDA recall notice. Yet despite this knowledge, Fresenius withheld that information from the medical community at large and even, for a period of time, from its own dialysis centers such as the one that provided Ms. Hill's treatment.

II. STATEMENT OF VENUE AND JURISDICTION

12. This Court has jurisdiction over this matter pursuant to 28 U.S.C. § 1332. There is complete diversity of citizenship between Plaintiffs and Defendants, and the amount in controversy exceeds $75,000.00.

13. Venue is proper in this jurisdiction under 28 U.S.C. § 1391. Defendants reside and have their principal place of business in Massachusetts and are subject to personal jurisdiction in this judicial district.

III. PARTIES

14. Plaintiffs Wilmarine Hill and Larry Hill at all times relevant to this complaint were residents of the State of Ohio over the age of 18 years of age.

15. Defendant Fresenius USA, Inc. (collectively "Fresenius" with Defendants named in paragraphs 16-19) is a corporation of the state of New York with its principal place of business at 920 Winter Street, Waltham, Massachusetts 02451. At all relevant times herein, Fresenius was in the business of promoting, manufacturing, labeling, and distributing NaturaLyte Liquid and GranuFlo Acid Concentrates. Defendant does business throughout the United States and at all relevant times hereto, marketed, promoted, warranted and sold NaturaLyte Liquid and GranuFlo Acid Concentrates in Ohio.

16. Defendant Fresenius Medical Care Holdings, Inc. d/b/a "Fresenius Medical Care North America" (collectively "Fresenius" with Defendants named in paragraphs 15-19) is a corporation of the state of Massachusetts with its principal place of business at 920 Winter Street, Waltham, Massachusetts 02451. At all relevant times herein, Fresenius was in the business of promoting, manufacturing, labeling, and distributing NaturaLyte Liquid and GranuFlo Acid Concentrates. Defendant does business throughout the United States and at all relevant times hereto, marketed, promoted, warranted and sold NaturaLyte Liquid and GranuFlo Acid Concentrates in Ohio.

17. Defendant Fresenius USA Manufacturing, Inc. (collectively "Fresenius" with Defendants named in paragraphs 15-19) is a corporation of the state of Delaware with its principal place of business at 920 Winter Street, Waltham, Massachusetts 02451. At all relevant

times herein, Fresenius was in the business of promoting, manufacturing, labeling, and distributing NaturaLyte Liquid and GranuFlo Acid Concentrates. Defendant does business throughout the United States and at all relevant times hereto, marketed, promoted, warranted and sold NaturaLyte Liquid and GranuFlo Acid Concentrates in Ohio.

18. Defendant Fresenius USA Marketing, Inc. (collectively "Fresenius" with Defendants named in paragraphs 15-19) is a corporation of the state of Delaware with its principal place of business at 920 Winter Street, Waltham, Massachusetts 02451. At all relevant times herein, Fresenius was in the business of promoting, manufacturing, labeling, and distributing NaturaLyte Liquid and GranuFlo Acid Concentrates. Defendant does business throughout the United States and at all relevant times hereto, marketed, promoted, warranted and sold NaturaLyte Liquid and GranuFlo Acid Concentrates in Ohio.

19. Defendant, Fresenius USA Sales, Inc. (collectively "Fresenius" with Defendants named in paragraphs 15-19) is a corporation of the state of Delaware with its principal place of business at 920 Winter Street, Waltham, Massachusetts 02451. At all relevant times herein, Fresenius was in the business of promoting, manufacturing, labeling, and distributing NaturaLyte Liquid and GranuFlo Acid Concentrates. Defendant does business throughout the United States and at all relevant times hereto, marketed, promoted, warranted and sold NaturaLyte Liquid and GranuFlo Acid Concentrates in Ohio.

IV. COMMON FACTS

A. GranuFlo in Dialysis

1. GranuFlo and Dialysis Complications.

20. Sudden cardiac arrest, also known as cardiopulmonary arrest, is the most dangerous complication of dialysis. Unfortunately, the Fresenius dialysis product GranuFlo, a

product given to a majority of hemodialysis patients in the United States, makes patients several times more susceptible to cardiac arrest.

21. Dialysates such as GranuFlo are administered to patients to maintain the balance of acid and base in the blood. This is because the kidneys of dialysis patients do not remove enough acid from the blood, which may consequently become too acidic, a serious condition known as acidosis. To prevent acidosis, substances known as "dialysates" are administered during dialysis to neutralize acid in the blood. A dialysate is a solution that includes both a bicarbonate and an acid. A bicarbonate is an alkali, also known as a "base," and serves to neutralize or "buffer" some of the excess acid in the dialysis patient's blood. The acid, or acetate, used in dialysates also serves to buffer some of the excess acid in the patient's blood. This is because the liver quickly converts acetate to bicarbonate.

22. As a result, dialysis patients actually receive bicarbonate from two sources – from the bicarbonate concentrate used in the dialysate and, indirectly, from the acid concentrate used in the dialysate, which is then quickly converted into bicarbonate by the liver. Taken together, the bicarbonate delivered to the patient through the bicarbonate concentrate and the bicarbonate converted by the liver from the acetate are known as the "total buffer." These elements must be carefully balanced because both low pH levels ("acidosis") and high pH levels ("alkalosis") are extremely dangerous – and an excess total buffer can lead to alkalosis.

B. How GranuFlo May Harm Dialysis Patients

23. The acid concentrate traditionally used in dialysis has been a liquid acid. GranuFlo is a newer product composed of a dry acid powder which replaces the traditional liquid concentration. The powder form is more concentrated than the liquid form leading to reduced shipping and storage costs compared to liquid formulations. There is, however, an additional

and crucial difference between the traditional acid concentrates and GranuFlo. GranuFlo, unlike liquid acid concentrates, uses sodium diacetate, the powder form of acetic acid.

24. The problem is that sodium diacetate – the material used in Fresenius's GranuFlo product – produces higher levels of bicarbonate in the body than more traditional dialysates. When an acetate is combined with bicarbonate to make a dialysate, the combination results in no net increase in the amount of bicarbonate. Stated simply, the acetate "consumes" an amount of bicarbonate equal to the amount that is produced by the liver as a result of the introduction of the acetate. However, the introduction of sodium diacetate actually results in a net increase in the amount of bicarbonate being delivered by nearly twice that of any other product.

25. The machines used to control the dialysis process track the levels of bicarbonate being introduced into the patient's body through a "bicarb value" displayed on the machine. This value, however, includes only the bicarbonate introduced via the bicarbonate concentrate – it does not include the bicarbonate being produced by the acetate.

26. The result, as recognized in an internal Fresenius memo, is that the use of GranuFlo in the formulations given to dialysis patients can cause the blood of patients treated with GranuFlo to become not merely neutral but basic, a condition known as alkalosis which has been found to increase the risk of cardiac arrest several fold. The FDA found this danger sufficient to issue a Class 1 FDA recall of GranuFlo, their most serious form of recall.

C. Fresenius Promoted Its Product As Safe

27. Fresenius Medical Care Holdings, Inc. is the largest division of Fresenius Medical Care AG, headquartered in Germany, and is the largest dialysis services and products company in both the U.S. and the world.

28. Fresenius promoted GranuFlo as the "safest" product:

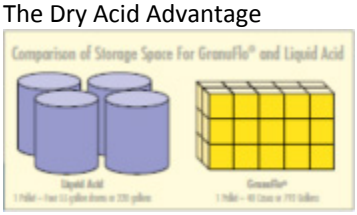
GranuFlo

Formulations – Procedure Card – Material Important Prescription Information

GranuFlo® is the most-widely prescribed dry acid product in the dialysis industry today. Its unique composition of evenly distributed electrolytes is the result of our exacting production technology. With GranuFlo's distinctive proportional component blend in each bag, **you have made the safest choice for onsite concentrate mixing.**

Safe for your patients and your staff, our utilization of dry Sodium Diacetate eliminates the need for hazardous liquid glacial Acetic Acid, making GranuFlo **the safest dry** acid product. Other risks of injury to staff can be reduced as well by eliminating the handling of heavy liquid acid drums weighing 570 lbs. A case of GranuFlo weighs less than 50 lbs, with individual bags weighing approximately 15 lbs each.

The Dry Acid Advantage



GranuFlo Dry Acid Dissolution System eliminates 55-gallon drums providing your clinic with valuable storage space (4 times the concentrate with the same amount of space). One pallet consisting of four (4) 55-gallon drums is equivalent to 220 total gallons of liquid acid concentrate. One pallet of GranuFlo dry acid concentrate consisting of 48 cases is equivalent to 792 gallons - a ratio of nearly 4 to 1.

The cost advantage of dry acid, allows us to deliver the most competitive price per gallon over liquid concentrate, while at the same time, **offering superior clinical outcomes**. (Emphasis added.)

29. Fresenius is vertically integrated in its business environment in that Fresenius both owns thousands of dialysis clinics and it also manufactures the dialysis machines and nearly all the medical products used in dialysis care including dialyzers, blood lines, needles, dialysis concentrate, etc.

30. The Fresenius products division "sells" products not only to its own clinics' division, but also sells them to many of its leading competitors, including DaVita, DCI, Renal Ventures, and many others.

D. Fresenius Is Aware of the Increased Risk of Cardiac Arrest From GranuFlo

31. Through information and belief, an internal memo from Fresenius dated November 4, 2011, indicated that Fresenius had knowledge that there was a significant increased risk of cardiac arrest and even death during hemodialysis treatments associated with their GranuFlo dialysis concentrate product that contains sodium diacetate.

32. Top Fresenius executives knew about the increased risk of cardiac arrest and death during hemodialysis treatments associated with their GranuFlo dialysis concentrate product since its introduction.

33. When Fresenius finally decided to reveal the problem, top Fresenius executives chose not to properly report these complications or GranuFlo specific risks to the FDA or other government agencies.

34. When the clinical problem finally became irrefutably evident to the Fresenius Medical Services division around 2010, top Fresenius executives also decided to withhold these complications or GranuFlo specific risks from non-Fresenius physicians and clinics that were using the GranuFlo product.

35. Fresenius decided to hide, mislead, and obscure information about the extreme patient safety hazard associated with the use of GranuFlo and NaturaLyte products in order to maintain market share as well as to minimize and diffuse the legal risks for Fresenius.

36. Ultimately, after the correlation between GranuFlo use, alkalosis, and cardiopulmonary arrest was made by Fresenius, the company chose to make this information,

and associated urgent medical recommendations, solely available to its own physicians and clinics.

37. The internal Fresenius memo which was circulated on November 4, 2011, specifically recommended action for patients with pre-dialysis bicarbonate levels of >28mEq/L and especially for those who also had pre-dialysis serum potassium levels of <4 mEq/L. This 6-page internal FMC memo shows that for at least 15 months, Fresenius did not share this information with the thousands of non-Fresenius physicians and clinics that were using the GranuFlo product.

38. The November internal Fresenius memo went on to state that, "[r]ecent analyses performed using FMCNA hemodialysis (HD) patient safety data confirms that alkalosis is a significant risk factor associated with cardiopulmonary (CP) arrest in the dialysis unit, independent of and additive to the risk of CP arrest associated with pre-dialysis hypokalemia. The major cause of metabolic alkalosis in dialysis patients is inappropriately high dialysate total buffer concentration. As recommended in previous communications, physicians should individualize dialysate bicarbonate and total buffer prescriptions. We further recommend that predialysis serum bicarbonate level of >24 mEq/L should prompt immediate review of dialysate bicarbonate prescription."

39. The internal November memorandum went on to further state in its "summary of findings" that: "The current analysis determined that: '*borderline elevated pre-dialysis bicarbonate levels and overt alkalosis are significantly associated with 6 to 8 fold greater increase of cardiopulmonary arrest and sudden cardiac death in the dialysis facility*.' (italics in original)... In light of these troubling findings, we strongly recommend that physicians adjust dialysate bicarbonate prescriptions monthly for individual patients, with immediate attention to

patients with serum pre-dialysis bicarbonate level of >24 mEq/L." The memo further urges that this dangerous issue "needs to be addressed urgently."

40. On March 27, 2012, Fresenius received an inquiry from the FDA specifically about GranuFlo-related products and alkalosis.

41. Only after the FDA inquiry did Fresenius provide a scientifically-ambiguous, 2-page memorandum, with far less actionable information, to its non-Fresenius customers. This correspondence did not mention any patient blood levels and failed to discuss in any manner the most at-risk population of all, "acute" dialysis patients.

42. The March 29th memo to non-Fresenius clinics and physicians contained only one of ten medical references that the FMC internal memo did. The March 29th memo also bundled the risks of GranuFlo with another FMC acid concentrate product, NaturaLyte.

43. Through information and belief, the GranuFlo product line saw steadily increased market share since its introduction in 2003 and as of 2012 was used by the majority of nearly 400,000 hemodialysis patients in the U.S.

44. In the internal November 4, 2011 Fresenius memo, GranuFlo use was associated with increased serum bicarbonate levels and alkalosis, as well as the increased possibility of cardiopulmonary arrests.

45. Also in the internal November 4, 2011 Fresenius memo, the company noted that its own patients' serum pre-dialysis bicarbonate levels had gradually increased from 2004 to 2011. Despite Fresenius' knowledge of this patient safety risk, more non-Fresenius clinics were actively being converted to the GranuFlo product even after knowledge of the risks that were made clear in the internal November 4, 2011 Fresenius memo.

46. Despite these patient safety issues and possible Federal Trade Commission and FDA violations and penalties, Fresenius product sales divisions continued to aggressively market the product and routinely bundled GranuFlo with other Fresenius products for pricing discounts.

47. GranuFlo formulations are unique in the dialysis treatment world in that they use sodium diacetate. Through this formulation, GranuFlo doubles the amount of acetate in dialysate compared to formulations made with acetic acid. Instead of adding 4 mEq/L of acetate, it adds 8 mEq/L. This means that for dialysates made from GranuFlo, the total buffer level is 8 mEq/L higher than the bicarbonate level delivered from the bicarbonate concentrate.

48. This increased buffer level with GranuFlo products was never communicated by Fresenius to treating clinicians, physicians, or nurses and could lead to significantly increased bicarbonate levels and the associated risks of heart attack, cardio pulmonary arrest, and/or sudden cardiac death.

E. GranuFlo is Recalled

49. THE NEW YORK TIMES reported on June 14, 2012, that the Food and Drug Administration was investigating whether the nation's largest operator of dialysis centers violated federal regulations by failing to inform customers of a potentially lethal risk connected to one of its products.

50. The article quoted an FDA official:

> "Personally, I'm troubled by the fact that Fresenius on its own initiative didn't notify its entire customer base of this particular concern," Steven Silverman, director of compliance for the F.D.A.'s medical devices division, said in an interview this week.
>
> Mr. Silverman said the agency could issue a warning letter to Fresenius if it determined the company should have reported the safety concerns. But even if the company had no legal obligation, he said, "Candidly, I just think it's bad business and not in the interest of public health to sit on information about risks."

51. The article also quoted:

> Dr. Thomas F. Parker III, chief medical officer at Renal Ventures, a dialysis chain that uses Fresenius products, agreed. "If the data was sufficient to warn their doctors, then all users of the product should have been made aware of it.

52. On March 29, 2012, the U.S. Food and Drug Administration (FDA) issued a Class 1 recall of GranuFlo and NaturaLyte, dialysis products manufactured by Fresenius Medical Care. The use of either product can result in high bicarbonate levels that can cause metabolic alkalosis – a significant risk associated with low blood pressure, hypokalemia, hypoxemia, hypercapnia, and cardiac arrhythmia, which may culminate in cardiopulmonary arrest and death.

53. Class 1 recalls are the most serious type of recall and involve situations in which there is a reasonable probability that use of these products will cause adverse health consequences – or death.

F. Studies Show 941 Deaths

54. FMC conducted a case-control study that evaluated risk factors in hemodialysis patients who suffered from cardiopulmonary arrest in FMC facilities compared to other dialysis patients within the same facilities between January 1 and December 31, 2010. This study identified 941 patients in 667 Fresenius facilities who had cardiopulmonary (CP) arrests within the facilities. Looking at the data for these 941 patients, the study found that the patients' risk of cardiopulmonary arrest was up to *six times* higher if they had an elevated pre-dialysis bicarbonate level.

V. CAUSES OF ACTION

FIRST CAUSE OF ACTION: FAILURE TO WARN

55. Plaintiffs reallege and incorporate herein by reference each of the foregoing paragraphs of this Complaint as though fully set forth herein.

56. Defendants' NaturaLyte and/or GranuFlo products reached Wilmarine Hill without substantial change in the condition in which they left the possession of the Defendants. The products were used and administered in the manner which had been contemplated.

57. The NaturaLyte and GranuFlo manufactured and supplied by the Defendants was defective due to inadequate warnings and/or instructions. Defendants knew and/or should have known that its NaturaLyte and GranuFlo products had not been adequately tested prior to marketing and that those products created significant risks of serious bodily harm and death to consumers – risks which were reasonably foreseeable at the time of sale and/or could have been discovered by way of reasonable testing prior to marketing the product.

58. Defendants had a duty to, but failed to adequately warn dialysis patients including Wilmarine Hill, dialysis providers, and the FDA, of such risks and/or provide adequate instructions that would allow its products to be used without creating an unreasonable risk of harm to the consumer. Had it issued such warnings or instructions, the injuries suffered by Wilmarine Hill as well as thousands of similarly situated dialysis patients throughout the United States, could have been reduced or avoided altogether. Had Fresenius provided adequate instructions or warnings, dialysis providers could have altered their prescription practices, adjusted their dialysis machines, or otherwise taken steps to ensure that they were accurately calculating the amount of bicarbonate being introduced into their patients' systems, thus preventing unintentional overdoses of bicarbonate. Fresenius's omission of those warnings or instructions, however, rendered the product not reasonably safe.

59. Fresenius knew and/or should have known of its products' increased dangerous propensities as compared to other similar and comparable alternatives. Those increased risks

were known or discoverable through reasonable investigation to Defendants at the time of sale, yet Fresenius failed to warn regarding these increased risks.

60. Fresenius, one of the world's largest manufacturers of dialysis concentrate products, is held to the level of knowledge of an expert in the field. Fresenius also had had specific actual knowledge of the dangerous risks and side effects of NaturaLyte and GranuFlo of which it failed to warn Wilmarine Hill, and/or protect her by providing adequate warnings or instructions to dialysis providers using its products such as the clinic that administered those products to Wilmarine Hill. Indeed, even after Fresenius knew of its products' dangerous propensities, it continued to market the product as safe and effective.

61. Wilmarine Hill did not have the same knowledge as Defendants and no adequate warning was communicated to her. The risks posed by Fresenius' products were not obvious or generally known.

62. Fresenius had a continuing duty to warn consumers including Wilmarine Hill, dialysis providers and the FDA of the risks and dangers associated with its products. It negligently and/or wantonly breached its duty as follows:

a. Failed to include adequate warnings with the hemodialysis products that would alert consumers to the dangerous risks and serious side effects of NaturaLyte and GranuFlo.

b. Failed to include adequate instructions with the hemodialysis products that would allow its products to be used in a manner that would not create unreasonable risks to consumers.

c. Failed to provide adequate warnings and instructions after the Defendants knew or should have known of the significant risks of heart attack, cardiac arrest, sudden cardiac death, stroke, and other adverse medical conditions from the use of NaturaLyte and GranuFlo.

d. Failed to inform Wilmarine Hill that NaturaLyte and GranuFlo had not been adequately and thoroughly tested for safety as a hemodialysis treatment.

63. As a direct and proximate result of Defendants' failure to warn regarding the significant risks associated with its NaturaLyte and GranuFlo products that were manufactured, sold, supplied, and introduced into the stream of commerce by Defendants or to provide adequate instructions for their use as set forth above, Wilmarine Hill sustained injuries including but not limited to a heart attack, and endured profound pain and suffering and mental anguish.

SECOND CAUSE OF ACTION: BREACH OF IMPLIED WARRANTIES

64. Plaintiffs reallege and incorporate herein by reference each of the foregoing paragraphs of this Complaint as though fully set forth herein.

65. When Defendants Fresenius placed NaturaLyte and GranuFlo into the stream of commerce, they knew that the dialysis concentrates would be used for dialysis treatments just as Wilmarine Hill received. Indeed, Fresenius specifically manufactured, distributed, marketed and promoted NaturaLyte and GranuFlo for that purpose. In doing so, Fresenius impliedly warranted to the users of NaturaLyte and GranuFlo – which included Wilmarine Hill, dialysis providers such as the provider that administered Defendants' products to Ms. Hill prior to her heart attack, as well as to other similarly situated dialysis patients and dialysis providers and to the FDA – that its products were safe and fit for their intended use in dialysis treatment.

66. In fact, NaturaLyte and GranuFlo were not of merchantable quality and were not safe or fit for their intended use. As described above, NaturaLyte and GranuFlo were unreasonably dangerous and unfit for the ordinary purposes for which they were used because

they created elevated levels of bicarbonate leading to significantly increased risks of serious or even fatal complications. Moreover, as described above, Fresenius failed to provide adequate instructions or warnings regarding these risks, which constitutes a further breach of its implied warranties.

67. NaturaLyte and GranuFlo breached the warranties because they were unduly dangerous and not fit for their intended purpose as a result of defects in the design of the product and/or due to Fresenius's failure to provide adequate instructions or warnings regarding its products.

68. Wilmarine Hill, as well as her dialysis provider (and other similarly situated dialysis providers) and the FDA reasonably relied upon the Fresenius's skill and judgment in impliedly warranting that NaturaLyte and GranuFlo were of merchantable quality and safe and fit for their intended use in dialysis treatment.

69. Fresenius placed its NaturaLyte and GranuFlo products into the stream of commerce in an unsafe, defective and inherently defective condition. Those products were intended to and did reach users including Wilmarine Hill and other similarly situated dialysis patients and medical professionals without a substantial change in the condition in which Fresenius sold the products.

70. As a direct and proximate result of the breach of implied warranties by the Defendants, Wilmarine Hill sustained injuries including but not limited to a heart attack, and endured profound pain and suffering and mental anguish.

THIRD CAUSE OF ACTION: BREACH OF EXPRESS WARRANTY

71. Plaintiffs reallege and incorporate herein by reference each of the foregoing paragraphs of this Complaint as though fully set forth herein.

72. Defendants expressly warranted that NaturaLyte and GranuFlo were safe and fit for use in dialysis treatment, that they did not produce any dangerous side effects in excess of the risks associated with other acid concentrates used in dialysis treatments, that the products were adequately tested, and that the side effects they did produce were accurately reflected in the warnings accompanying the product.

73. The NaturaLyte and GranuFlo manufactured and provided by Defendants did not conform to these express representations because they were not safe and were unfit for the use for which they were intended. As described more fully above, NaturaLyte and GranuFlo were defective in that their use in the manner and for the purposes intended creates an unreasonable risk of serious or even fatal complications and side effects in dialysis patients. The products therefore are unsafe and unfit for use in dialysis treatment. Fresenius did not disclose or warn of these defects, complications or side effects, nor did it disclose that it had failed to adequately test its products prior to marketing them and warranting their fitness for use in dialysis treatments.

74. Wilmarine Hill, as well as other similarly situated dialysis patients, dialysis providers and medical professionals making decisions regarding dialysis patients' treatments, reasonably relied upon the skill, judgment, representations and express warranties of Fresenius as described above.

75. Fresenius knew or should have known that its warranties were false, misleading and untrue in that NaturaLyte and GranuFlo were not safe or fit for their intended purposes and in fact caused serious and even fatal complications and side effects that were not identified or included in warnings by Fresenius.

76. Fresenius thus breached the express warranties described above because their products NaturaLyte and GranuFlo were defective and did not contain adequate warnings.

77. As a direct and proximate result of the breach of express warranties by the Defendants, Wilmarine Hill sustained injuries including but not limited to a heart attack, and endured profound pain and suffering and mental anguish.

FOURTH CAUSE OF ACTION: FRAUDULENT CONCEALMENT

78. Plaintiffs reallege and incorporate herein by reference each of the foregoing paragraphs of this Complaint as though fully set forth herein.

79. Defendants Fresenius intentionally, willfully, wantonly or recklessly deceived Wilmarine Hill and others, her prescribing physicians and healthcare providers, the medical, scientific, pharmaceutical and healthcare communities, the FDA, and similarly situated dialysis patients and the public in general, by concealing from them the true and material facts concerning NaturaLyte and GranuFlo, which Fresenius had a duty to disclose.

80. Fresenius knew as early as 2005 that NaturaLyte and GranuFlo were not safe, fit, and effective for use in dialysis treatment. Furthermore, Defendants Fresenius were aware that the use of NaturaLyte and GranuFlo was hazardous to health, and that NaturaLyte and GranuFlo have a significant propensity to cause serious injuries to users including, but not limited to cardiac arrest, stroke and other serious and even fatal complications.

81. Fresenius was under an obligation to disclose the true facts regarding NaturaLyte and GranuFlo, including the increased risk of alkalosis and resulting increased risks serious and fatal complications and side effects because the disclosure of those facts was necessary to keep its prior statements – including statements that its products were the "safest choice" and offered "superior clinical outcomes" as well as express warranties regarding the safety and efficacy of its products – from being misleading. Moreover, the non-disclosed facts regarding the safety and fitness of NaturaLyte and GranuFlo for use in dialysis is basic to and goes to the very essence of the transaction.

82. Fresenius knew, but intentionally, willfully, wantonly or recklessly concealed and suppressed the true facts concerning NaturaLyte and GranuFlo with the intent to defraud Wilmarine Hill and other similarly situated dialysis patients, her prescribing physicians and healthcare providers, the medical, scientific, pharmaceutical and healthcare communities, and the public in general.

83. Specifically, Fresenius fraudulently concealed or intentionally, willfully, wantonly or recklessly omitted the following facts, each of which was material, necessary to make Fresenius' prior statements regarding the safety and efficacy of NaturaLyte and GranuFlo not misleading, and/or basic to the purpose of the transaction, and each of which was known only to Fresenius at the time:

a. That NaturaLyte and GranuFlo were not as safe as other acid concentrates;

b. That the risks of serious adverse side effects and complications associated with the use of NaturaLyte and/or GranuFlo were higher than those associated with the use of other acid concentrates in dialysis;

c. That Fresenius had not adequately tested risks of adverse side effects and complications associated with the use of NaturaLyte and/or GranuFlo prior to marketing the products for use in dialysis;

d. That the use of NaturaLyte and/or GranuFlo in connection with dialysis treatments resulted in elevated bicarbonate levels;

e. That the use of NaturaLyte and/or GranuFlo in connection with dialysis treatments resulted in increased instances of alkalosis, a condition it knew could result in dangerous side effects and complications including but not limited to cardiopulmonary arrest,

electrolyte imbalances, hypokalemia, hypoxemia, hypercapnia, cardiac arrhythmias, coma, stroke, hypotension and even death;

f. That NaturaLyte and/or were defective in that they caused dangerous side effects, including but not limited to cardiopulmonary arrest, electrolyte imbalances, hypokalemia, hypoxemia, hypercapnia, cardiac arrhythmias, coma, stroke, hypotension and even death at a much higher rate than other acid concentrates used in dialysis;

g. That the administration of NaturaLyte and/or GranuFlo to dialysis patients resulted in dangerous side effects, including but not limited to cardiopulmonary arrest, electrolyte imbalances, hypokalemia, hypoxemia, hypercapnia, cardiac arrhythmias, coma, stroke, hypotension and even death;

h. That physicians, dialysis providers, and or health care facilities administering NaturaLyte and/or GranuFlo should monitor patients' bicarbonate levels more frequently than is common with other acid concentrates used in dialysis;

i. That there existed procedures, adjustments and calculations that could render the use of NaturaLyte and/or GranuFlo for dialysis more safe and/or that could reduce or eliminate the increased risk of alkalosis and associated serious or even fatal side effects and complications;

j. That Fresenius had instructed its own dialysis clinics and treatment centers to follow procedures, adjustments and calculations that could render the use of NaturaLyte and/or GranuFlo for dialysis more safe and/or that could reduce or eliminate the increased risk of alkalosis and associated serious or even fatal side effects and complications while at the same time withholding that information from competing dialysis treatment facilities, from the medical community, from the FDA, and from the general public (including dialysis patients); and

k. That NaturaLyte and/or GranuFlo were designed, manufactured, marketed, produced and distributed negligently.

84. The foregoing facts were material, and indeed were central to the purpose of the underlying transaction – which was to receive effective and safe dialysis treatment. Wilmarine Hill would not have used NaturaLyte and GranuFlo if she had known the true facts concerning the dangers of NaturaLyte and GranuFlo.

85. Plaintiff and her doctors, dialysis providers and/or hospitals, like other similarly situated dialysis patients and their treating medical professionals, reasonably relied on the accuracy and completeness of the statements made by Fresenius regarding the safety and efficacy of its NaturaLyte and/or GranuFlo products, and neither knew nor reasonably could have known about the facts which were concealed and omitted by Fresenius.

86. As a result of the foregoing fraudulent and deceitful conduct by Defendants Fresenius as set forth above, Wilmarine Hill sustained injuries including but not limited to a heart attack, and endured profound pain and suffering and mental anguish.

FIFTH CAUSE OF ACTION: NEGLIGENT MISREPRESENTATION

87. Plaintiffs reallege and incorporate herein by reference each of the foregoing paragraphs of this Complaint as though fully set forth herein.

88. Defendants represented to Wilmarine Hill, her prescribing physicians and healthcare providers, the medical, scientific, pharmaceutical and healthcare communities, the FDA, and similarly situated dialysis patients and the public in general, that its NaturaLyte and GranuFlo products had been adequately tested and were safe and effective for their intended use, including statements that its products were the “safest choice” and offered “superior clinical outcomes” as well as express warranties regarding the safety and efficacy of its products. Those representations were, in fact, false.

89. Fresenius was under an obligation, but failed to exercise ordinary care in assessing the accuracy of its representations and warranties regarding the safety and efficacy of NaturaLyte and GranuFlo in dialysis treatments. Fresenius knew or should have known as early as 2005 that NaturaLyte and GranuFlo were not safe, fit, and effective for use in dialysis treatment. Furthermore, Defendants Fresenius knew or should have known that the use of NaturaLyte and GranuFlo was hazardous to health, and that NaturaLyte and GranuFlo have a significant propensity to cause serious injuries to users including, but not limited to cardiac arrest, stroke and other serious and even fatal complications. Fresenius further knew or should have known that it had not conducted sufficient testing prior to marketing NaturaLyte and GranuFlo to adequately assess their safety or fitness for use in dialysis treatment.

90. The foregoing facts were material, and indeed were central to the purpose of the underlying transaction – which was to receive effective and safe dialysis treatment. Wilmarine Hill would not have used NaturaLyte and GranuFlo if she had known the true facts concerning the dangers of NaturaLyte and GranuFlo.

91. Plaintiff and her doctors, dialysis providers and/or hospitals, like other similarly situated dialysis patients and their treating medical professionals, reasonably relied on the accuracy and completeness of the statements made by Fresenius regarding the safety and efficacy of its NaturaLyte and/or GranuFlo products, and neither knew nor reasonably could have known that Fresenius' statements regarding its product constituted misrepresentations, or were false and misleading.

92. As a result of the foregoing negligent and wrongful conduct by Defendants Fresenius as set forth above, Wilmarine Hill sustained injuries and damages as alleged herein.

SIXTH CAUSE OF ACTION: FRAUD / DECEIT

93. Plaintiffs reallege and incorporate herein by reference each of the foregoing paragraphs of this Complaint as though fully set forth herein.

94. Fresenius fraudulently, intentionally, willfully or recklessly misrepresented to the Plaintiff, the FDA, the medical community and general public, the safety of NaturaLyte and GranuFlo. Fresenius made numerous statements and represented NaturaLyte and GranuFlo as being safe for use in hemodialysis. Indeed, Fresenius represented its products as being safest choice" that offered "superior clinical outcomes." Yet at the same time it was making these and similar representations, it was in possession of or recklessly disregarded information obtained through its own research and testing that in fact those products were not safe and led to serious and even fatal complications and side effects.

95. Fresenius made misrepresentations regarding the safety and efficacy of its products through numerous means, including advertisements, websites, marketing materials, product literature and other information it provided to the medical community and to dialysis patients including Ms. Hill.

96. In making these statements, Fresenius intentionally and knowingly provided false information regarding its products. Fresenius represented that their warnings, instructions, training and product information were complete and accurate. They were not. It represented that its products were safe and effective when used as instructed, when in fact it knew that its products lead to dangerous elevations in bicarbonate levels without the imposition of additional procedures. It represented that their product resulted in the same total buffer effect as other acid concentrates when in fact it resulted in a substantially higher buffer effect than traditional liquid acid concentrates.

97. At the time it was making these representations, Fresenius knew that its representations were false or recklessly failed to ascertain the truth or falsity of its representations. On information and belief, Fresenius knew by 2005 that its GranuFlo product resulted in an increased contribution of bicarbonate to a dialysis patient than was specified in its instructions and materials, thus necessitating the imposition of special procedures and controls in order to avoid dangerous elevations in bicarbonate levels and the associated serious or even fatal complications. It thus knew that NaturaLyte and GranuFlo had defects, dangers, and characteristics that were other than what it was representing to the FDA, the medical community and the consuming public, including Wilmarine Hill. Yet it continued to represent its products as safe and effective, without instituting any changes in the procedures it recommended for the use of its products. Specifically, Fresenius misrepresented to Wilmarine Hill, the FDA, the medical community and the consuming public that:

a. NaturaLyte and GranuFlo, when used as recommended, were safe for use in dialysis treatments.

b. NaturaLyte and GranuFlo were fully and adequately tested.

c. NaturaLyte and GranuFlo had no serious undisclosed adverse effects on blood pressure, the heart, or cardiopulmonary physiology.

d. NaturaLyte and GranuFlo were safe and effective.

98. Defendants Fresenius knew that these representations were false, deceptive and misleading, and made them with the intent to defraud, deceive and mislead, knowing that Wilmarine Hill and other similarly situated dialysis patients would rely on them, leading to the use of NaturaLyte and GranuFlo. Defendants Fresenius knew that physicians, dialysis clinicians, and nurses had been told the same false and fraudulent information about NaturaLyte and

GranuFlo, and that Wilmarine Hill, other similarly situated dialysis patients, and their treating physicians, dialysis clinicians, and nurses would rely on information, advertisements and statements made by Defendants Fresenius about the use, safety and efficacy of NaturaLyte and GranuFlo.

99. At the time of Defendants' fraudulent misrepresentations Wilmarine Hill was unaware of the falsity of the statements being made and believed them to be true.

100. Wilmarine Hill justifiably relied on and/or was induced by the misrepresentations made by Defendants regarding the safety and use of NaturaLyte and GranuFlo, and in fact, used NaturaLyte and GranuFlo as recommended. Had Fresenius not made these fraudulent, false and misleading statements, Ms. Hill would not have used its products and her medical providers would not have administered it.

101. Defendants Fresenius had a post-sale duty to warn Wilmarine Hill and the public about the potential risks and complications associated with NaturaLyte and GranuFlo in a timely manner.

102. The misrepresentations and active concealment by the Defendants Fresenius constituted a continuing tort against Wilmarine Hill.

103. As a direct and proximate result of the misrepresentations and concealment of the Defendants Fresenius as set forth above, Wilmarine Hill sustained injuries and suffered the injuries and damages as alleged herein.

SEVENTH CAUSE OF ACTION: NEGLIGENCE

104. Plaintiffs reallege and incorporate herein by reference each of the foregoing paragraphs of this Complaint as though fully set forth herein.

105. Fresenius had a duty to exercise reasonable care in designing, researching, manufacturing, marketing, supplying, promoting, packaging, sale and /or distribution of

NaturaLyte and/or GranuFlo and introducing such products into the stream of commerce. This duty included the duty to ensure that its products would not cause users to suffer unreasonable, dangerous side effects.

106. Fresenius failed to exercise ordinary care in carrying out these duties, and therefore breached them. Fresenius knew or should have known that NaturaLyte and/or GranuFlo, when used in for their ordinary purpose and in the intended manner, caused elevated levels of bicarbonate in dialysis patients, and created an unreasonable risk of dangerous and even lethal side effects including cardiac arrest, stroke, and other grave and serious conditions. Fresenius further knew or should have known that it had failed to adequately review, test and study its NaturaLyte and/or GranuFlo products to adequately ascertain their safety and efficacy prior to introducing them into the stream of commerce.

107. Fresenius had a duty to adequately warn, train, instruct and/or monitor treating physicians and dialysis treatment facilities to ensure that their NaturaLyte and/or GranuFlo products were being properly used and/or administered.

108. Defendants failed to meet those duties, and did not provide adequate warnings, training, instruction or monitoring to physicians and facilities administering its products. Indeed, Fresenius intentionally or negligently withheld information regarding the proper use and administration of its products from treating physicians and medical facilities for years. It later provided instructions regarding the proper use of its products to its own dialysis facilities, while still failing to provide those instructions to competing dialysis facilities and treating physicians.

109. Fresenius' negligence, including the wrongful acts and omissions of its agents, servants and/or employees, includes:

a. Manufacturing, producing, promoting, and/or designing NaturaLyte and/or GranuFlo without adequately or thoroughly testing them to determine whether and under what conditions they were safe for use despite knowing the significant dangers its products could pose to dialysis patients;

b. Selling NaturaLyte and/or GranuFlo without adequately or thoroughly testing them to determine whether and under what conditions they were safe for use despite knowing the significant dangers its products could pose to dialysis patients;

c. Failing to provide adequate instructions regarding safety precautions and procedures to be observed in the administration and use of NaturaLyte and/or GranuFlo;

d. Failing to adequately and accurately warn the Plaintiff, Mr. Hill, the medical community, the FDA and the general public including other similarly situated dialysis patients of the risks and dangers of NaturaLyte and/or GranuFlo;

e. Advertising and recommending the use of NaturaLyte and/or GranuFlo without sufficient knowledge as to their dangerous propensities;

f. Representing that NaturaLyte and/or GranuFlo were safe for use in dialysis treatment as intended, when in fact they were not safe;

g. Negligently representing that NaturaLyte and/or GranuFlo were as or more safe and effective as other acid concentrates used in dialysis;

h. Negligently designing, manufacturing, producing, or assembling NaturaLyte and/or GranuFlo in a manner that was dangerous to their users;

i. Negligently communicating the dangers and risks associated with the use of NaturaLyte and/or GranuFlo to the Plaintiff, to Mr. Hill, to the medical community, to the FDA and to the general public including other similarly situated dialysis patients.

j. Concealing, misrepresenting or failing to reveal information to the Plaintiff, to Mr. Hill, to the medical community, to the FDA and to the general public including other similarly situated dialysis patients suggesting that NaturaLyte and/or GranuFlo were unsafe, dangerous and/or did not conform to FDA regulations;

k. Concealing, misrepresenting or failing to reveal information to the Plaintiff, to Mr. Hill, to the medical community, to the FDA and to the general public including other similarly situated dialysis patients suggesting that NaturaLyte and/or GranuFlo presented more severe risks and dangers than other acid concentrates used in dialysis;

l. Negligently handling the recall of NaturaLyte and/or GranuFlo.

m. Violated statutes, ordinances, rules and/or regulations governing the manufacture, marketing and/or testing of their products that were intended to ensure the safety of those products and the accurateness of representations about those products;

n. Under-reporting, underestimating and downplaying the serious and even lethal risks and dangers associated with the use of NaturaLyte and/or GranuFlo in dialysis.

110. Despite the fact that Fresenius knew or should have known that NaturaLyte and/or GranuFlo caused unreasonably dangerous side effects, including but not limited to cardiac arrest, stroke and even death among other serious conditions, Defendants continued to market, manufacture, sell and distribute NaturaLyte and/or GranuFlo to consumers, including Ms. Hill, and to members of the health care community including Ms. Hill's healthcare providers.

111. Defendants' actions, by violating statues, ordinances and/or other rules and regulations, constituted negligence *per se*.

112. Defendants' negligence was the proximate cause of the injuries and damages alleged herein.

EIGHTH CAUSE OF ACTION: STRICT PRODUCTS LIABILITY

113. Plaintiffs reallege and incorporate herein by reference each of the foregoing paragraphs of this Complaint as though fully set forth herein.

114. At all times herein mentioned, Fresenius designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and/or distributed NaturaLyte and/or GranuFlo as described above, which was administered to and/or used by the Plaintiff.

115. Fresenius expected NaturaLyte and/or GranuFlo to and those products did reach the usual consumers, handlers, and persons coming into contact with said products without substantial change in the conditions in which they were produced, manufactured, sold, distributed, and marketed by Fresenius.

116. At all times relevant to this action, NaturaLyte and/or GranuFlo were in an unsafe, defective, and inherently dangerous condition, which were dangerous to users, and in particular, Wilmarine Hill. Plaintiff could not, by the exercise of reasonable care, have discovered the defects described above or perceived their danger. Fresenius, on the other hand, knew or could have discovered through reasonable investigation that such products were defective and unsafe, particularly when used in the form and manner prescribed by Defendants.

117. The acid concentrates, NaturaLyte and/or GranuFlo, designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Fresenius were defective in design or formulation in that, when they left the hands of the manufacturer and/or suppliers, the foreseeable risks exceeded the benefits associated with the design or formulation of NaturaLyte and/or GranuFlo, were unreasonably dangerous, and were more dangerous than an ordinary consumer would expect.

118. During the dialysis treatment provided to Ms. Hill, which ultimately led to her experiencing a heart attack, the NaturaLyte and/or GranuFlo products were being used for the purposes and in the manner normally intended.

119. Defendants had a duty to create products that were not unreasonably dangerous for their normal, intended use. Instead, Defendants did create products, specifically NaturaLyte and/or GranuFlo, which were unreasonably dangerous when put to their normal intended uses.

120. The acid concentrates, NaturaLyte and/or GranuFlo, designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants were manufactured defectively in that NaturaLyte and/or GranuFlo left the hands of Defendants in defective conditions and were unreasonably dangerous to their intended users. They reached their intended users in the same defective and unreasonably dangerous conditions.

121. Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed defective products which created an unreasonable risk to the health of consumers and to Mr. Hill in particular, and Defendants are therefore strictly liable for the injuries and damages alleged herein.

NINTH CAUSE OF ACTION: DECEPTIVE TRADE AND BUSINESS PRACTICES ACT VIOLATIONS[1]

122. Plaintiffs reallege and incorporate herein by reference each of the foregoing paragraphs of this Complaint as though fully set forth herein.

123. Defendants are headquartered in, and engaged in trade and commerce within the Commonwealth of Massachusetts. Defendants' wrongful conduct described herein, including

[1] Plaintiffs have provided, concurrent with the filing of this Complaint, written notice pursuant to M.G.L. § 93A. Plaintiffs will amend this Complaint to specifically assert claims under § 93A once the thirty day waiting period has passed.

breaches of express and implied warranties and fraudulent conduct, constitute deceptive and unfair business practices under Massachusetts law.

124. As described herein, Fresenius represented that its products had characteristics, uses and benefits that they did not have.

125. As further described herein, Fresenius represented that its products were of a particular standard, quality and grade they either knew or should have known was not of the standard, quality or grade described.

126. Defendants failed to provide accurate disclosures of all material information before Ms. Hill and her dialysis providers chose to use Fresenius' products.

127. Defendants' willful and knowing withholding of important safety information and critical product information constitutes a violation of Massachusetts law.

128. Fresenius actively, knowingly, and deceptively concealed its knowledge of its products' dangerous propensities and life-threatening risks. This conduct shows bad faith and constitutes an unfair and deceptive practice.

129. The acts and practices described above were and are likely to and did mislead the general public, including Wilmarine Hill, and therefore constitute unfair business practices. This conduct includes, but is not limited to:

a. Knowingly or recklessly publishing instructions and product material containing inaccurate and incomplete information;

b. Knowingly providing crucial safety instructions only to dialysis clinics owned or operated by Fresenius, while simultaneously withholding that information from competing third party dialysis providers using the Fresenius products;

c. Knowingly or recklessly misrepresenting the nature, quality and characteristics of the product; and

d. Providing information about the nature, use and effect of its products in a manner that was misleading and did not include all information available to Fresenius regarding its products' impacts on bicarbonate levels in dialysis patients and the associated risks.

130. Representing to Wilmarine Hill, her physicians, the FDA, and the general public that NaturaLyte and GranuFlo were safe, fit, and effective for their intended use, knowing that said representations were false, and concealing from Wilmarine Hill, her physicians, the FDA, and the general public that NaturaLyte and GranuFlo had the serious propensity to cause injuries to users;

131. Promoting and marketing NaturaLyte and GranuFlo as safe for use in hemodialysis treatment even though the Defendants knew it to be false, and even though the Defendants had no reasonable grounds to believe it to be true; and

132. Purposely and intentionally downplaying and understating the health hazards and risks associated with NaturaLyte and GranuFlo.

133. These practices constitute unlawful, unfair and fraudulent business acts or practices under Massachusetts law, as well as unfair, deceptive, untrue and misleading advertising.

134. The unlawful, unfair and fraudulent business practices of Fresenius described above have had a deleterious effect on the public interest and have caused substantial injury to consumers. Fresenius' unethical, unscrupulous and unconscionable conduct is contrary to public policy as established by the statutes and common law of Massachusetts.

135. As a result of their conduct described above, Defendants have been and will be unjustly enriched. Specifically, Defendants have been unjustly enriched by receipt of hundreds of millions of dollars in ill-gotten gains from the sale of NaturaLyte and GranuFlo, sold in large part as a result of the acts and omissions described herein.

136. Because of fraudulent misrepresentations made by Defendants as detailed above, and the inherently unfair practice of committing a fraud against the public by intentionally misrepresenting and concealing material information, the acts of Defendants described herein constitute unfair or fraudulent business practices.

137. Plaintiffs seek an order of this court to compel the Defendants to provide restitution, to disgorge the monies collected and profits realized by the Defendants as a result of their unfair business practices, for injunctive relief calling for Defendants to forever cease and desist such unfair business practices in the future, for all statutory, direct and consequential damages resulting from this breach (including multiple damages), and for fees and costs.

TENTH CAUSE OF ACTION

(LOSS OF CONSORTIUM)

138. Plaintiffs reallege and incorporate herein by reference each of the foregoing paragraphs of this Complaint as though fully set forth herein.

139. At all times relevant hereto Plaintiff Larry Hill was the spouse of Wilmarine Hill.

140. As a direct and proximate result of the conduct of Defendants described herein, Mr. Hill has been deprived of the normal comfort, society, aid, services, consortium, and support of his spouse, and has otherwise suffered economic and other loss, the extent of which will be more fully adduced at the trial of this matter.

VI. RELIEF REQUESTED

WHEREFORE, Plaintiffs pray for judgment against Defendants FRESENIUS USA, INC., FRESENIUS USA MANUFACTURING, INC., FRESENIUS USA MARKETING, INC., FRESENIUS USA SALES, INC., FRESENIUS MEDICAL CARE HOLDINGS, INC. d/b/a FRESENIUS MEDICAL CARE NORTH AMERICA, jointly and severally, and as appropriate to each cause of action alleged as follows:

A. Past and future general damages, the exact amount of which has yet to be ascertained, in an amount which will conform to proof at time of trial;

B. Past and future economic and special damages according to proof at the time of trial;

C. Loss of earnings and impaired earning capacity according to proof at the time of trial;

D. Medical expenses, past and future, according to proof at the time of trial;

E. For past and future mental and emotional distress, according to proof;

F. Punitive or exemplary damages according to proof at the time of trial;

G. Restitution and other equitable relief;

H. Attorney's fees;

I. For costs of suit incurred herein;

J. For pre-judgment interest as provided by law; and

K. For such other and further relief as the Court may deem just and proper.

DEMAND FOR JURY TRIAL

Plaintiffs, through undersigned counsel, hereby demand a jury trial on all counts in this Complaint.

DATED: ~~March 27, 2013~~ April 1, 2013

By: Lauren Guth Barnes

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